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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/742,622 | 12/21/00 | COLE | C JBP-534 |

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| EXAMINER | |
|---|---|
| YU, G | |
| ART UNIT | PAPER NUMBER |
| 1619 | 5 |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/742,622 | COLE ET AL. | |
| | Examiner | Art Unit | |
| | Gina C Yu | 1619 | |

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 May 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15)☒ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(A) Claims 1-6, 9-11, 13-17, 21 – 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Yu et al (U.S. Pat. No. 4,197,316).

Yu et al. disclose method to treat dry skin, using topical composition which comprise one or more alpha hydroxy acids, esters thereof, and their ammonium salts. See abstract. Compositions containing ethanolamine salt of glycolic acid, and triethanolamine salt of lactic acid are disclosed. See Examples 1-5. The pH of the solutions range 4.4- 4.7, which meets claim 9. The organic amines for the invention include N-methylethanolamine, N-ethylethanolamine, and triethanolamine. See col. 3, lines 14 – 25. A solution containing 2 grams of glycolic acid, 2 grams of citric acid, and ethanolamine is disclosed in Example 5, which meets claims 4-6.

(B) Claims 1-6, 9-11, 13-17, 20 – 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Scott et al. (U.S. Pat. No. 4,234,599).

Van Scott discloses composition and method and composition to treat skin keratoses, which comprises one or more alpha hydroxy acids and/or their salts with amines. The composition may be in the form of gel, solution, lotion, cream, or ointment having pH of 3.0 –

7.5, which meets claims 9 and 20. See col. 4, lines 50 – 52. For the alpha hydroxy acids, employing the glycolic acid, malic acid, or citric acid, and alpha hydroxy acids and their organic salts is disclosed. The preferred amines for the invention which include N-methylethanolamine, N-ethylethanolamine, triethanolamine, and choline are also disclosed. See col. 3, lines 35 – 56. The reference illustrates compositions containing glyclic acid ethanolamine salt 5% cream, lactic acid triethanolamine salt 7% lotion, or tartaric acid triethanolamine salt 5% cream, which meets claim 11.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

(A) Claims 7, 8, and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al., as applied to claims 1-6, 9-11, 13-17, 21 – 23 above, and further in view of Znaiden et al. (U.S. Pat. No. 5,523,090).

Yu et al. is discussed above. The reference lacks the specific example of using glycolic acid and malic acid and their weight ratio.

Znaiden et al. (U.S. Pat. No. 5,523,090) disclose skin treatment compositions for improving skin strength and firmness, which comprise salts of alpha hydroxy acids and caffeine. The reference teaches that the presence of the salt would depend on the pH of the solution, and discloses solutions with pH of 5.5. or less See col. 5, lines 35 – 48; Example 3, and claims 2 and 7. While a composition containing 1:1 weight ratio of malic acid and lactic acid is disclosed in example 12, the reference fails to teach the specific example of combining malic acid and glycolic acid. The reference, however, teaches that the most preferred acids in the invention include glycolic acid and lactic, and the reference further teaches that the choice of these alpha hydroxy acid depends on the efficacy of compositions in increasing percutaneous absoprtion. See col. 5, lines 43 – 45. Furthermore, in Example 4, the solubility test of caffeine in various alpha hydroxy acids indicate the compatible solubilibity of caffein in malic, lactic, and glycolic acids.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of the combined references by adding malic acid and glycolic acid, as suggested by Znaiden et al., and used it to treat aging skin and to promote firmness of the facial skin, because of the expectation to have succeed in producing a skin care composition which would provide good penetration action and effectively deliver active

ingredients. Also, one skilled in the art would have been able to discover the optimum or workable range of the weight ratio between the alpha hydroxy acids through routine experiments, which does not render patentability.

(B) Claims 7, 8, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Scott et al., as applied to claims 1-6, 9-11, 13-17, 20 – 23 above, and further in view of Yu et al. and Znaiden et al.

Van Scott et al. is discussed above. The reference lacks a specific example of combining glycolic acid with citric or malic acid as required by instant claims 7, 8, and 18, and 19.

Yu et al. and Znaiden et al. are discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Van Scott's composition by mixing glycolic acid with citric or malic acid, as taught by Yu et al. or as suggested by Znaiden et al, because of the expectation to have successfully produced a composition for aging skin which provide good penetration action.

(C) Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. and Znaiden et al., or alternatively over Van Scott, Yu et al., and Znaiden et al., as applied to claims 1-11, and 13-23 above, and further in view of Quan et al (U.S. Pat. No. 6,180,133 B1).

The combined references lacks a teaching of using the composition with the articles as required by claim 12.

Quan et al. teach an adhesive, matrix-patch for treating wrinkle. The adhesive contains mixture of vitamins, alpha hydroxy acids or their salts, and glycerine. See col. 3, line 45 – col. 4, line 63; col. 4, lines 44 – col. 5, line 23. The reference teaches that the administration of the

composition with the patch system is more effective than by hand, and provides the enhanced absorption of the therapeutic components into the skin. See col. 7, lines 7 – 35.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the composition in the combined references with adhesive patch, as suggested by Quan et al., because of expectation to have successfully administered the therapeutic components in the combined references more effectively.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11, and 13-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4-7,10 –12, and 14-16 of copending Application No. 09/777,737. Although the conflicting claims are not identical, both claims are directed to skin care compositions comprising alpha hydrxy acids or salts thereof and identical groups of akanolamines.

This is a provisional obviousness-type double patenting rejection.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-305-3593. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu
Patent Examiner
June 17, 2001

DIANA DUDASH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER